



Idaho State Board of Pharmacy

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August 16, 2012

Name
Address
City, St Zip

Re: Prescriber Drug Outlets

In August of 2011, the Board of Pharmacy (Board) notified all prescribers via letter of changes to Idaho Code and administrative rule concerning certain controlled substance (CS) data to be submitted for each CS dispensed, as well as annual CS inventory, prospective drug review and counseling requirements. The purpose of this letter is to notify you of 2012 changes to Idaho Code and administrative rules that further effect dispensing prescribers.

One new area of Board registration is termed the Prescriber Drug Outlet and is defined as: "A drug outlet in which prescription drugs or devices are dispensed directly to patients under the supervision of a prescriber, except where delivery is accomplished only through on-site administration or the provision of drug samples." It is important to note that administering and prescribing are not included in this definition and thus do not require registration as a drug outlet. These rules only pertain to prescribers who dispense, which is defined as: "the preparation and delivery of a prescription drug...in a suitable container appropriately labeled...". Prescriber drug outlets are required to pay a \$35 fee with registration and renew annually by June 30th. Please note that only one registration per facility is required, not per prescriber within the facility. Prescriber drug outlets are required to abide by applicable general practice standard rules, including the following:

- Drugs must be stored in accordance with USP-NF requirements in an area maintained and secured appropriately to safeguard product integrity and protect against product theft or diversion. The link to the USP-NF web site is: <http://www.usp.org/usp-nf>
- Expired, deteriorated, adulterated, damaged, or contaminated drugs must be removed from stock and isolated for return, reclamation, or destruction.
- Prescription drugs must be dispensed in packaging materials that preserve their integrity, cleanliness, and potency.
- Once removed from the premises from which it was dispensed, a drug must not be accepted for return, unless it meets several requirements, including being unit dose packaged.
- Each controlled substance registrant must maintain a current, complete, and accurate record of each controlled substance manufactured, imported, received, ordered, sold, delivered, exported, dispensed, or otherwise disposed of by the registrant.
- A potential recipient of a controlled substance must first be positively identified, via a government issued ID, or the controlled substance must not be dispensed. Exceptions include the dispensing being paid for by an insurer, dispensing to institutionalized patients, and if the patient is personally and positively known. Documentation requirements exist.
- Documentation must be created and retained sufficient to evidence compliance with the offer to counsel and the counseling requirements of 2011 changes to Section 54-1739, Idaho Code, which also require a prospective drug review with each dispensing. Said terms are defined in Section 54-1705, Idaho Code.
- Some prescribers may be utilizing Automated Dispensing and Storage Systems (ADS), which are defined as mechanical systems that perform operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing, or distribution of drugs and that

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- collect, control, and maintain transaction information. ADS are subject to extensive regulation and require additional registration. Additionally, some prescribers may be engaging in sterile product preparation, which requires a separate registration and an onsite Board inspection prior engaging in such activity.

Specific rule language <http://adminrules.idaho.gov/rules/current/27/0101.pdf> and prescriber drug outlet applications http://bop.idaho.gov/forms/2012_05_16_DRUG_OUTLET_app_05152012.pdf can be found on the Board's web site: www.bop.idaho.gov/. Questions can be directed to the Board by e-mailing info@bop.idaho.gov or by calling (208)334-2356.

Sincerely,



Mark Johnston, R.Ph.
Executive Director